Docket No.: 0933-0284PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Seppo SARNA et al.

Application No.: Confirmation No.: N/A

Filed: Concurrently Herewith Art Unit: N/A

For: A METHOD FOR PREDICTING THE STATE OF THE GASTRIC MUCOSA Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The PTO is requested to use the amended sheets/claims attached hereto (which correspond to Article 19 amendments or to claims attached to the International Preliminary Examination Report (Article 34)) during prosecution of the above-identified national phase PCT application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Dated: September 5, 2006

Respectfully submitted,

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Attachment(s)

Claims

1. Method for assessing or predicting the state of the gastric mucosa in a subject by determining, in said subject, the probability for the gastric mucosa belonging to at least one gastric mucosa class, the method comprising
   - measuring, from a sample of said subject, the pepsinogen I (PGI) and gastrin-17 (G-17) analyte concentrations, as well as determining the presence or concentration of a marker for *Helicobacter pylori*,
   - entering the data so obtained in a data processing system comprising an operating system, a database and means for transceiving and processing data, the said data processing system being adapted to determine the probability for the gastric mucosa belonging to the at least one gastric mucosa class, the gastric mucosa class being selected from the group of classes consisting of normal (N), antrum atrophy (A), antrum and corpus atrophy (AC), corpus atrophy (C) and superficial or non-atrophic gastritis (S), based on the data entered as well as on predefined clinical data in the database, the information so generated by the data processing system being indicative of the state of the gastric mucosa in said subject.

2. The method according to claim 1 for assessing a change in the state of the gastric mucosa, the method comprising repeating the determination of the probability for the at least one gastric mucosa class, and comparing the probabilities so obtained with the earlier determined probabilities in order to provide information relating to the change in the state of the gastric mucosa.

3. The method according to any one of the preceding claims, wherein the predefined clinical data in the database comprises data obtained from a reference population group by gastroscopic study and determination of the PGI and G-17 analytes and *Helicobacter pylori* marker in said reference population group.

4. The method according to any one of the preceding claims wherein the probabilities are determined using a statistical method for calculation of the classification probabilities.

5. The method according to claim 4 wherein the statistical method for the calculation of the classification probabilities is a multinominal logistic regression method (MLR).

6. The method according to any one of the preceding claims, comprising the further step of using the generated information for providing a diagnosis and/or a suggestion for further treatments or examinations.

7. The method according to any one of the preceding claims, wherein the *Helicobacter pylori* marker is a *Helicobacter pylori* antibody, the concentration of which is measured from the sample.

8. The method according to any one of the preceding claims, wherein the *Helicobacter pylori* marker is the *Helicobacter pylori* antigen, the presence of which is determined in the sample.

9. The method according to any one of the preceding claims, wherein the gastrin value measured is the stimulated gastrin-17 value (G-17st), or both the gastrin-17 and the stimulated gastrin-17.

10. The method according to any one of the preceding claims, wherein, in addition, the concentration of the analyte pepsinogen II (PGII) is measured, and the ratio PGI/PGII is used in the statistical calculation.

11. The method according to claim 1, wherein the analytes are measured from a body fluid, such as a serum whole blood, urine, saliva or lacrimal fluid sample, especially a serum sample.

12. The method according to any one of the preceding claims, wherein the data processing means comprise a display, and the information generated is displayed on the display.

13. A kit comprising means for determining, from a sample, the pepsinogen I and gastrin-17 concentration, and the concentration or presence of a *Helicobacter pylori* marker, as well as a computer program product embodied on a computer readable medium and comprising computer code means adapted to determine a probability for a gastric mucosa class, the gastric mucosa class being selected from the group of classes consisting of normal (N), antrum atrophy (A), antrum and corpus atrophy (AC), corpus atrophy (C) and superficial or non-atrophic gastritis (S), based on measured values for said analytes and/or marker as well as predefined clinical data in a database, and to provide information in response to said determination and optionally other entered data, when run on a computer.

14. The kit according to claim 13, wherein the predefined clinical data comprises data obtained from a reference population group by gastroscopic studies and determination of values for PGI and G-17 analytes and *Helicobacter pylori* marker from said reference population group.

15. A computer program product embodied on a computer readable medium and comprising computer code means adapted to determine a probability for a gastric mucosa class, the gastric mucosa class being selected from the group of classes consisting of normal (N), antrum atrophy (A), antrum and corpus atrophy (AC), corpus atrophy (C) and superficial or non-atrophic gastritis (S), based on measured values for the PGI and G-17 analytes and *Helicobacter pylori* marker, as well as predefined clinical data in a database, and to provide information in response to said determination and optionally to other entered data, when run on a computer.